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UNDER SECRETARY OF COMMERCE FOR INTELLECTUAL PROPERTY AND
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In re Application of	:
JANNES et al	:
Serial No.: 09/787,000	: Petition Decision
Filing Date: 13 March 2001	:
Attorney Docket No. 2752-33	:

This letter is in response to the Petition under 37 CFR 1.144, filed on 10 March 2003 to review examiner's decision on the restriction requirement. The delay in acting upon this petition is regretted.

BACKGROUND

A review shows this file is the national stage application of PCT/EP99/07065, filed 22 September 1999, which claims priority to EPO application 99870203.1, filed 24 September 1998.

Applicants corrected the improper dependencies of the original 12 claims with Amendment A, filed 18 October 2001.

In Paper No. 6, mailed 15 January 2002, the claims were restricted into two groups as follows:

> Group I, claims 1-5, drawn to a method of detecting infection by amplification with a primer mixture and detecting the amplified products with a probe.
>
> If applicant elects group I, applicant must also select one primer from Tables 2 and 4 for each of the required regions of claim 1 and select one probe from Tables 3, 4 or 5.

Group II, claims 6-12, drawn to primers, probes and kits.

Applicants' elected Group I, and selected SEQ ID Nos. 17 and 18 as the pair of primers and SEQ ID Nos. 8, 11, 26 and 28 as probes with traverse, in Paper No. 8 filed 14 March 2002.

In Paper No. 9, mailed 22 May 2002, the examiner noted the election of Group I and SEQ ID Nos. 17 and 18 as primers. The Examiner noted the selection of SEQ ID Nos. 8, 11, 26, and 28 as probes.

Table 4 shows that the elected primers, SEQ ID Nos. 17 and 18, correspond to *Mycoplasma pneumonia.*

Tables 3 and 4 show that SEQ ID No. 8 corresponds to *Adenovirus*, SEQ ID No. 11 corresponds to *Parainfluenza virus* 1, SEQ ID No. 26 corresponds to *Mycoplasma pneumonia* and SEQ ID No. 28 corresponds to *Chlamydia pneumonia.* The election was incomplete, in as far as no primer sets were elected to correspond with probes detecting *Adenovirus, Parainfluenza virus* 1 or *Chlamydia pneumonia.* Further, the election was incomplete, in that specific primer set for each of the organisms in Tables 3 and 4 was missing. The Examiner pointed out that Applicant was requested to elect one primer set from Tables 2 and 4, for each of the regions required in Claim 1.

The examiner conceded that applicants' traversal concerning a single probe is persuasive. Applicants were again invited to elect one probe for each of the pathogens to be detected. Because applicants were unable to elect via telephone, the following restriction requirement was set forth to correct a typographical error (emphasized here in bold, underlined text):

> Group I, claims 1-5, drawn to a method of detecting infection by amplification with a primer mixture and detecting the amplified products with a probe.
>
> If applicant elects group I, applicant must also select one primer **set** from Tables 2 and 4 for each of the required pathogens in claims 1 and 3 and select one probe from Tables 3, 4 or 5 for each of the required pathogens in claims 1 and 3.
>
> Group II, claims 6-12, drawn to primers, probes and kits.

In Paper No. 10, filed on 24 June 2002, applicants responded with an election, with traverse, of a single probe for each of the microorganisms to be detected:

Enterovirus	SEQ ID No. 4
Influenza A	SEQ ID No. 5
Influenza B	SEQ ID No. 6

Adenovirus	SEQ ID No. 8
Parainfluenza 1	SEQ ID No. 11
Parainfluenza 3	SEQ ID No: 13
RSV (rsv1)	SEQ ID No. 14
Mycoplasma pneumoniae for rRNA region	SEQ ID No. 15
Chlamydia pneumoniae for rRNA region	SEQ ID No. 16
Mycoplasma pneumoniae for spacer region	SEQ ID No. 26
Chlamydia pneumoniae for spacer region	SEQ ID No. 28
Bordetella pertussis	SEQ ID No. 29
Bordatella parapertussis/bronchiseptica	SEQ ID No. 30
Rvs2	SEQ ID No. 31
Rsv6	SEQ ID No. 32
Rsv7	SEQ ID No. 33
Rsv8	SEQ ID No 34.

Applicants again failed to elect one **set** for primers for each of the required regions in Tables 2 and 4. As such the election should have been treated as non-responsive. However in the apparently well-intentioned interest of moving ahead with prosecution, the examiner erroneously withdrew all the other probes and primers from examination, except for SEQ ID No. 15, which the Examiner identified as the first probe corresponding to elected invention, now SEQ ID Nos. 18 and 19. Claims 6-12 were withdrawn from consideration as being directed to non-elected invention. Claims 3 and 4 were objected to for informalities. Claims 1-5 were examined and rejected under 35 U.S.C. 112, second paragraph and 35 U.S.C. 103(a) as being unpatentable in view of Jannes et al, Class et al, Paton et al, Kinchington et al, Saikku et al, Gilbert et al, Fluitt et al, second Jannes et al and Echevarria et al. SEQ ID No. 19 was indicated as being free of the prior art.

On 20 March 2003, applicants responded to the Office action with an amendment which canceled all original claims and added method claims 13-22 and product claims 23-29. Applicants also filed the Petition under consideration herein.

DISCUSSION

The file and petition have been carefully considered. The Petition requests that the restriction requirement to a single primer set and single probe be withdrawn. The response states that applicants want to "protect all possible primer combinations that allow simultaneous amplification." It is noted that while applicants have a right to try and protect all possible primer combinations, typically only one set of primer and probe combinations will be examined within a single patent application. See MPEP 803.04, which is directed to the examination of sets of molecules.

Applicants are correct in that the invention requires a primer set for each gene to be used for the simultaneous detection of the nine gene regions in original Claim 1. The Examiner recognized the need to elect a specific primer for each gene region in the first Restriction Requirement, see Paper No. 6, page 2, "As discussed above, applicant must

elect one primer for each of the required regions in claim 1 and one probe." In response, Applicants elected the pair of primer sequences SEQ ID No 17 and 18 and the one primer 18, drawn to *Mycoplasma pneumonia*. (Paper No. 8, page 4). Applicant then elected multiple probe sequences 8, 11, 26 and 28, directed to three other organisms, in addition to *Mycoplasma pneumonia* (Paper No. 8, page 5). It is noted that probes corresponding to SEQ ID Nos. 8, 11, 26 and 28 are not directed to detection of the elected nucleotide sequence that would be amplified using primers 17 and 18. Furthermore, specific primer sets and their corresponding probes for each of the organisms listed in Tables 3, 4 and 5 were not elected. As such, the first election was incomplete.

In the second restriction requirement, the Examiner acknowledged the election of Group I and SEQ ID Nos. 17 and 18. The Examiner then clarified that applicants needed to select "a primer **set** for each of the pathogens recited in claim 1." With regard to the probes, applicants were requested to elect one probe for each of the pathogens detected.

In response to the second restriction requirement, applicants changed their election to the pair of primers SEQ ID No. 18 and 19, however, they erred in not electing one pair for each of the gene regions or pathogens being detected. Applicants did elect 17 different probes, one corresponding to each of the 17 pathogens or gene regions that may be detected. However, without an election of the specific primers needed to amplify out the various gene regions, the election of the specific probes was insufficient.

Next, the examiner erred in considering applicants' second election as fully responsive. The Examiner considered the elected primer set, SEQ ID No.18 and 19 and the elected probe corresponding to that set, SEQ ID No. 15, as the elected invention. The examiner improperly withdrew methods of using the other probes and primers from consideration as being directed to non-elected inventions.

In response to the first Office action on the merits, applicant erred in canceling all claims directed to the original invention and presenting new claims. For the reasons set forth below, the amendment filed 10 March 2003 is considered non-responsive.

Original claim 1 is set forth below.

> 1. Method for the detection of acute respiratory tract infection comprising the simultaneous amplification of several target nucleotide sequences present in a biological sample by means of a primer mixture comprising at least one primer set from each one of the following gene regions:
>
> -the F1 subunit of the fusion glycoprotein gene for RSV,
> -the hemagglutininnneuraminidase gene for PIV-1,
> -the 5' non-coding region of the PIV-3 fusion protein gene,
> -16S rRNA sequence for *M. pneumoniae*,
> -16S rRNA sequence for *C. pneumoniae*,
> -the 5' noncoding region for enterovirus,
> -the non-structural protein gene from influenza A,

-the non-structural protein gene from influenza B, and,
-the hexon gene for adenoviruses.

Newly added Claim 13 is set forth below.

> 13. A method according [sic, delete] for the detection of acute respiratory tract infection comprising the simultaneous amplification of several target nucleotide sequences [that, sic] may be present in a biological sample using a primer mixture which comprises at least one primer set from each one of the following gene regions:
>
> the F1 subunit of the fusion glycoprotein gene for RSV
> the hemagglutininnneuraminidase gene for PIV-1
> the 5'non-coding region of the PIV-3 fusion protein gene
> the non-structural protein gene from influenza A,
> the non-structural protein gene from influenza B,
> and said primer mixture further comprises at least one primer set from at least one of the following genes:
> 16S rRNA sequence for *M. pneumoniae*,
> 16S rRNA sequence for *C. pneumoniae*,
> the 5' noncoding region for enterovirus,
> the hexon gene for adenoviruses.

It is noted that original claim 1 was set forth in the format of

A method of detecting each of A, B, C, D, E, F, G, H and I.

Newly presented claim 13 appears to be of the format of

A method of detecting each of A, B, C, D and E, and one of F, G, H, or I.

On first reading, it appears that claim 13 requires detecting six gene regions, i.e., A, B, C, D, and E and one of (F, G, H, or I). However, new Claim 19, which depends from and should further limit Claim 13, states:

> 19. A method according to claim 13, wherein said primer set consists of SEQ ID Nos. 18 and 19.

The closed claim language "consists of" appears to limit claim 13 to the detection of a single gene region and allows for claim 13 to be interpreted as a method of detecting using one primer set, SEQ ID Nos. 18 and 19, corresponding to *M. pneumonia* primers. Thus it is not clear whether claim 13 is a method of detecting 6 gene regions, one of which by using SEQ ID Nos. 18 and 19, detecting six gene regions, all of which are detected using SEQ ID Nos. 18 and 19 or detecting only one gene region using SEQ ID Nos. 18 and 19. Moreover, Claim 19 is either improperly dependent by being broader in scope than independent claim 13 or claim 19 lacks proper antecedent basis for "said primer set" or claim 19 should recite "comprises" in place of "consists of." While these issues may be resolved during examination, it is important to have the invention well enough defined in the claim set so that a reasonable assessment of restriction is possible.

DECISION

The petition is **DISMISSED** for the reasons set forth above.

The election filed 24 June 2002 is considered non-responsive. Applicants did not elect a primer set for each of the gene regions or pathogens being detected.

The Office action mailed 10 September 2002 as Paper No. 11 has been vacated.

The Amendment filed 10 March 2003, as Paper No. 14 has not been entered as it cancels all claims drawn to the elected invention and adds claims which are not clearly drawn to the elected invention.

The claims as currently pending are the original claims as amended by Amendment A filed March 13, 2001.

Applicants are given one month to respond to the restriction requirement set forth in Paper No. 9, mailed 22 May 2003, or, if applicable, as may be extended by 37 CFR 1.136(a).

Any request for reconsideration of this decision must be filed by way of a renewed petition and must be filed within TWO MONTHS of the date of mailing of this decision in order to be considered timely.

Should there be any questions with regard to this letter, please contact Special Program Examiner Julie Burke by letter addressed to the Director, Technology Center 1600, P.O. Box 1450, Alexandria VA 22313-1450 or by telephone at (703) 308-7553 or by facsimile transmission at (703) 305-7230.

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